

REMARKS

At the outset, applicants would like to thank Examiner Young and Examiner Spear for their time and consideration of the present application at the interview of January 9, 2004 with Mr. Andrew Patch, Mr. Thomas Lundqvist, Mr. Anders Pettersson and the undersigned attorney. At the interview, the issues raised in the outstanding Official Action were discussed.

In the outstanding Official Action, claims 1-21 were rejected under 35 USC 103(a) as allegedly being unpatentable over NYSTROM in view of FINE et al. and STANLEY et al. This rejection is respectfully traversed.

It was agreed at the interview that NYSTROM fails to teach a pharmaceutical composition comprising an essentially water-free, ordered mixture of microparticles of fentanyl or a pharmaceutically acceptable salt thereof adhered to the surfaces of carrier particles, wherein the carrier particles are substantially larger than the microparticles and are water-soluble and a bioadhesion and/or mucoadhesion promoting agent is mainly adhered to the surfaces of the carrier particles.

As noted at the interview, the NYSTROM publication teaches a pharmaceutical composition, wherein a disintegrant is incorporated within a carrier (column 2, lines 22-30). The disintegrant must be a water-insoluble ingredient such as a

cellulose or starch derivative (column 3, lines 8-25). Nystrom discloses that the disintegrant is effective in causing the carrier particles to disintegrate or explode. This causes the particles and active ingredients to rapidly dissolve and disperse when coming into contact with water.

This stands in contrast to the claimed invention. In the claimed invention, water-soluble, non-disintegrating carrier particles are covered with a pharmaceutically active agent and a bioadhesive and/or mucoadhesive material. Upon administration, the composition quickly disintegrates into ordered units comprising a carrier, fentanyl or a pharmaceutically acceptable salt thereof, and a bioadhesive and/or mucoadhesive material.

By incorporating a bioadhesive and/or mucoadhesive material, these units initially adhere to the mucosal lining of the oral cavity. As the water-soluble carrier particles gradually dissolve, the fentanyl or a pharmaceutically acceptable salt thereof dissolves along with them. Thus, the claimed composition enables a pharmaceutically active agent to be targeted to the mucosal lining of the oral cavity.

As the NYSTROM publication incorporates an insoluble ingredient into a carrier particle and fails to teach a bioadhesive and/or mucoadhesive material mainly adhered to the surface of a carrier component, applicants believe that the NYSTROM publication teaches away from the claimed invention.

The FINE et al. and STANLEY et al publications are limited to the use of oral transmucosal fentanyl citrate (OTFC) in commercial uses. However, FINE et al. and STANLEY et al fail to disclose or suggest the structure of the claimed invention.

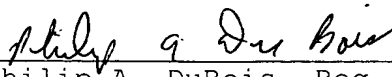
Thus, it is believed that the proposed combination of NYSTROM in view of FINE et al. and STANLEY et al. fails to render obvious the claimed invention. Indeed, the Interview Summary states that that "it was agreed that the NYSTROM reference does not read on the structure of the invention."

In view of the present response and the foregoing Remarks, therefore, it is believed that this application is now in condition for allowance, with claims 1-21, as presented. Allowance and passage to issue on that basis are accordingly respectfully requested.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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